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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,446	01/10/97	DUPRE J	223/051

HM12/0731

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EXAMINER	
NOLAN,P	
ART UNIT	PAPER NUMBER
1644	24

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/737,446	Dupre
Examiner	**Art Unit**
Patrick Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 15, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *38-47* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *38-47* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *23*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Part III DETAILED ACTION

1. This application is a 35 USC 371 national stage application of PCT/CA95/00287. The specification on page 1 should be amended to reflect the priority claim to the PCT application under 35 USC 371, PCT/CA95/00287.

2. Claims 38-47 are pending.

3. The request filed on 5-15-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/737,446 is acceptable and a CPA has been established. An action on the CPA follows.

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38-40, 43-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support in the originally filed claims or specification for the phrase "glucagon-like peptide 1 (7-36) amide agonist" and wherein said "glucagon-like peptide 1 (7-36) amide agonist delays gastric emptying". The term "agonist" has no support in the instant case or PCT/CA95/00287. Amendment of the base claim language from "analogue" of glucagon like peptide 1(7-37) or glucagon-like peptide 1(7-36)amide to any glucagon-like peptide 1 (7-36)amide agonist broadened Applicant's claimed language, said increase in claim breadth has no support in the originally filed Application or claims. A review of Stedman's medical dictionary 24th edition, clearly demonstrates that while an analogue is a compound that resembles another in structure (page 60 in particular), an agonist on the other hand is any drug capable of combining with receptors to initiate drug actions (page 34, in particular). Since the state of the art recognizes an agonist is not limited by structurally similarity while an analogue is, and

Applicant's specification is silent as to what an agonist or analogue encompasses, the amendment to the claims by removing analogue and inserting agonist is a broadening of the scope of the claimed invention which Applicant did not have written support for when the original specification and claims were filed. In addition the functional limitation of delaying gastric emptying only has written support for GLIP or glucagon-like peptide 1 (7-36) amide. Applicant points to pages 5-7 for support for said claim limitation, however, the written description supporting delaying gastric emptying for the GLP-1(7-36) amide agonist or analogues, was not found. The only support found was for the species GLP-1 (7-36) amide, not its analogues or agonists. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 38-47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-34 of copending Application No. 09/280,020.

The only claimed difference between the instantly filed claims and that of Application No. 09/280,020 is the route of administration of the GLP-1(7-36)amide agonist to treat type I diabetics. However, it is well within the purview of one of ordinary skill in the medicinal arts to optimize route of administration for individual patient compliance.

7. Any inquiry concerning this communication or earlier

communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
July 26, 2001